**RSH LLC**
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Houston, TX 77007
Phone: (713) 679-8657



**510(k) Number** _____

**Contact Person:** Amy Springs
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5121 Feagan St
Houston, TX 77007
Phone: (713) 679-8657

AUG 07 2013

**Summary Date:** June 3, 2013

**Product Trade Name:** RSH Biliary Stone Removal Device

**Common Name:** Dislodger, stone, biliary (LQR)
Catheter, biliary, diagnostic (FGE)

**Classification Name:** Biliary catheter and accessories (21 CFR 876.5010, Class 2)

**Predicate(s):** K102082/K041606 Extractor™ Retrieval Balloon catheters

**Intended Use:** The RSH Biliary Stone Removal Device is used for endoscopic removal of stones in the biliary system or for contrast injection while occluding the duct.

**Device Description:** The RSH Biliary Stone Removal Device is a single-use quad lumen polyurethane balloon catheter system which can be placed with or without the need of a guide-wire. The balloon is inflated using saline with the supplied 10ml syringe. The device is equipped with two flush ports, proximal and distal to the balloon, for contrast injection. The device is provided sterile.

The device is similar to the predicate device, except the balloon is polyurethane rather than latex, the fill is saline rather than air, and 4 lumens are used rather than ≤ 3 lumens. With more lumens, a somewhat larger balloon diameter range, 9 -25 mm, is achieved in one size rather than three sizes.

**Safety & Performance:** Equivalency was demonstrated through comparison to the predicate device, biocompatibility, and bench testing.

Biocompatibility testing consisted of cytotoxicity, sensitization and irritation, all of which yielded passing results.

Bench testing conducted is listed below along with conclusions:

| | |
|---|---|
| Balloon – Sizing/ Compliance, Multiple Inflation, Burst and Leak | All catheters performed through a range of 9mm – 25 mm without failure, leak, or rupture; inflated multiple times without failure, and inflated to 25mm without leakage. The working range was demonstrated. |
| Flush Volume | All catheters flushed lumens at or above the specified minimum flow rate demonstrating acceptable flushing capability. |

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| | |
|---|---|
| Manifold – Leak | All catheters held the minimum pressure at all three ports demonstrating acceptable leak resistance. |
| Balloon – Inflation/ Deflation | All catheters inflated and deflated as required demonstrating acceptable balloon performance.. |
| Manifold – Tensile Strength | All catheters met the minimum bond strength with 95% Confidence/ 95% Reliability demonstrating acceptable break resistance. |
| Model / Wire Loading, Endoscope Compatibility, Kink Resistance (flexibility) | All catheters loaded and advanced over a .035" guide wire, were delivered through the endoscope channel, endured a 90° deflection without kinking or breaking, and endured minimum tensile load without bursting when pulled back against endoscope. Acceptable handling characteristics were demonstrated.<br>All catheters and the predicated devices tested dislodged the stone without balloon rupture. The catheter demonstrated comparable effectiveness to the predicate device. |

**Conclusion:**

Based on the results of comparison, biocompatibility testing and bench testing summarized above, the RSH Biliary Stone Removal Device has been demonstrated to be acceptable for the intended use and substantially equivalent[1] to the predicate device in safety, effectiveness and performance.

[1] This document uses the term "substantial equivalent" as intended in 21 CFR 807.87 and not as defined in Title 36 of the U.S. Code.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 7, 2013

RSH LLC
% Amy Springs
Manager
5121 Feagan Street
HOUSTON TX 77007

Re: K131642
Trade/Device Name: RSH Biliary Stone Removal Device
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: LQR, FGE
Dated: June 3, 2013
Received: June 4, 2013

Dear Amy Springs,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K131642

Device Name: RSH Biliary Stone Removal Device

Indications for Use:

The RSH Biliary Stone Removal Device is used for endoscopic removal of stones in the biliary system or for contrast injection while occluding the duct.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

**(Division Sign-Off)**
**Division of Reproductive, Gastro-Renal, and Urological Devices**
**510(k) Number** K131642